Complying to Regulation (EC) 1907/2006

Material Safety Data Sheet
Clavubactin Tablets

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identification

Product name(s): Clavubactin 50/12.5mg Tablets
Clavubactin 250/62.5mg Tablets
Clavubactin 500/125mg Tablets

Product code(s): XVD225, XVD226 (50/12.5 mg 100 and 250 tablets respectively)
XVD228, XVD229 (250/62.5 mg 100 and 250 tablets respectively)
XVD231 (500/125 mg 100 mg tablets)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Veterinary medicinal product

Uses advised against: Not for human use. Refer to the product information leaflet

Reasons why uses advised against: Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

Company name: Animalcare Limited

Address: 10 Great Northway
York Business Park
Nether Poppleton
York
YO26 6RB
United Kingdom

1.4 Emergency telephone number

Daytime: +44 (0) 1904 487687

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008 This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

Hazard pictograms: Not applicable

Signal word: Not applicable

Hazard statements: Not applicable

Precautionary statements: Not applicable

Supplemental information: Not applicable

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC) None known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Substance name in the mixture	*CAS No*	*weight/tablet*
Amoxicillin trihydrate	[61336-70-7]	57.4/287/574 mg
Potassium clavulanate	[61177-45-5]	14.89/74.45/148.9 mg
Sodium saccharine	[128-44-9]	Proprietary
Microcrystalline cellulose	[9004-34-6]	Proprietary
Hypromellose	[9004-65-3]	Proprietary
Crospovidone	[94800-10-9]	Proprietary
Povidone	[9003-39-8]	Proprietary
Macrogol 6000	[74767-64-1]	Proprietary
Stearic acid	[57-11-4]	Proprietary
Titanium dioxide	[13463-67-7]	Proprietary
Colloidal silicon dioxide	[7631-86-9]	Proprietary
Magnesium stearate	[557-04-0]	Proprietary
Vanilla flavour	n.a.	Proprietary
Quinoline yellow	[8004-92-0]	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes: Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs

Skin: Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear

Inhalation: This route of exposure is unlikely. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention

4.2 Most important symptoms and effects, both acute and delayed

Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, diarrhoea. See section 11 for more information on health effects and symptoms

4.3 Indication of any immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Symptoms may be delayed. Medical treatment in cases of overexposure should be treated as an overdose of penicillin antibiotic. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre. This material may cause or aggravate allergy to penicillin antibiotics. The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting respiratory symptoms and including respiratory function testing. In the event of overexposure, individuals should receive post exposure health surveillance focused on detecting respiratory conditions and other allergy symptoms. Ocular symptoms may be indicative of allergic reaction. Pulmonary symptoms may indicate allergic reaction or asthma

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Foam. Dry chemical powder. Carbon dioxide (CO_2). Water

Unsuitable extinguishing media: None known

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Not flammable or combustible

Hazardous combustion products: Decomposition products may include the following materials: Carbon oxides (CO_x), nitrogen oxides (NO_x)

5.3 Advice for fire-fighters

Special protective equipment for firefighters: Self-contained breathing apparatus and full protective clothing must be worn in case of fire

Further information: Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS

Advice for emergency responders: If specialised clothing is required to deal with the spillage, take note of any information is section 8 on suitable and unsuitable materials

6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water of drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Large spills: Dike spilled material or otherwise contain material to ensure runoff does not reach a waterway

Small spills: Stop leak if safe to do so. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Flush away traces with water

6.4 Reference to other sections

See Section 1 for emergency contact information
See section 8 for personal protection
See Section 13 for additional waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling: Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment.

Hygiene measures: Observe good industrial hygiene practices

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep out of reach of children. Keep in the original packaging

Storage temperature: Store below 25 ^{o}C

Further information on storage conditions: Protect from direct incidence of light and in a dry place

7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. At this time, the other constituents have no known exposure limits

Substance name in the mixture	*Type*	*Value*
Amoxicillin trihydrate	15 min STEL	100 µg/m^3
Magnesium stearate	TWA	10 mg/m^3
Microcrystalline cellulose	TWA	10 mg/m^3

8.2 Exposure controls

Engineering measures: Good general ventilation should be sufficient to control worker exposure to airborne contaminants

Individual protection measures:

Hygiene measures: No specific measures identified

Eye/face protection: No specific measures identified

Skin/body protection: No specific measures identified

Hand protection: No specific measures identified

Respiratory protection: None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified respiratory protection equipment meeting EU requirements (89/656/EEC, 89/686/EEC), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization.

Environmental exposure controls: Consider the provision of containment around storage vessels

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance Solid tablet

Colour: Light yellow to white

Odour: No data available

Odour threshold: No data available

pH: No data available

Density: No data available

Melting point: No data available

Boiling point: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability: No data available

Water solubility: No data available

Partition coefficient: No data available

Auto-ignition temperature: No data available

Thermal decomposition: No data available

Viscosity: No data available

Vapour pressure: No data available

Vapour density:	No data available
Explosive properties:	No data available
Oxidizing properties:	The substance or mixture is not classified as oxidizing

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

10.4 Conditions to avoid

Avoid contact with incompatible materials

10.5 Incompatible materials

None Known

10.6 Hazardous decomposition products

Decomposition products may include the following materials: Carbon oxides nitrogen oxides

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Amoxicillin trihydrate LD_{50} >2000 mg/kg (Rat, oral) Potassium clavulanate LD_{50} >5000 mg/kg (Rat, oral) Magnesium stearate LD_{50} >2000 mg/kg (Rat, oral) Microcrystalline cellulose LD_{50} >2000 mg/kg (Rat, oral)
Chronic toxicity:	No data available
Skin irritation/sensitization:	Potassium clavulanate OECD 405 – Eye Non-irritant Amoxicillin trihydrate OECD 404 – Rabbit Non-irritant
Reproductive toxicity:	Potassium clavulanate NOAEL 75 mg/kg/day (Rat) Reproductive and developmental toxicity Potassium clavulanate NOAEL 150 mg/kg/day (Rat) Teratogenic and embryotoxicity
Carcinogenicity:	No data available
Mutagenicity:	Potassium clavulanate AMES test – Negative Amoxicillin trihydrate Mouse lymphoma cell assay – Negative Potassium clavulanate Mouse lymphoma cell assay – Negative

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

SECTION 14: TRANSPORT INFORMATION

Not regulated as dangerous goods

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This product has been authorised under the provisions of Directive 2001/82/EC

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

SECTION 16: OTHER INFORMATION

For animal treatment only
We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

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